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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 11, 1997

Our Reference: 29-51032

Jordan Bow, President
Royal Hawaiian Seafood
1155 Indiana Street
San Francisco, CA 94107

WARNING LETTER

Dear Mr. Bow:

On May 29 and 30, 1997, FDA Investigator Darla Bracy and FDA Chemist Lealand Lee conducted an inspection of your seafood processing facility at 1155 Indiana Street, San Francisco, California. During the inspection, FDA collected samples of tuna and swordfish. Results of analysis of those samples revealed that the lots of tuna and swordfish are violative, as follows:

Sample Number	Product	Findings
INV-97-732-236	Tombo Tuna	1/11 subs decomposed (Class 2) 10/11 subs decomposed (Class 3)
DI-97-732-237	Yellowfin Tuna	4/6 subs decomposed (Class 2)
INV-97-732-238	Swordfish	4/4 subs decomposed (Class 3) Methyl mercury : original: 2.9 ppm check: 3.3 ppm

INV-97-732-239	Swordfish	7/7 subs decomposed (Class 3) Methyl Mercury: original: 1.1 ppm check: 1.9 ppm additional: 1.6 ppm additional check: 1.8 ppm

Decomposed fish is deemed to be adulterated within the meaning of Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act. Fish containing methyl mercury in excess of 1.0 ppm is adulterated within the meaning of Section 402(a)(1) of the Act.

The receipt in interstate commerce of any food that is adulterated, and the delivery or proffered delivery thereof for pay or otherwise is prohibited under Section 301(c) of the Act. Adulteration of foods, while held for sale after receipt in interstate commerce, is prohibited by Section 301(k). Adulterated foods are subject to seizure as provided in Section 304 of the Act. Section 302 authorizes the government to seek injunctive relief to restrain violations of Section 301 of the Act.

We acknowledge your efforts to recall the four lots of adulterated fish. However, you must take prompt action to prevent future violations. Failure to promptly implement adequate corrections may result in regulatory action without further notice.

We have reviewed your letter, dated June 6, 1997, which responded to the FDA-483 issued on May 30, 1997. You propose to look into your suppliers' procedures of checking and handling products. This does not adequately address the problem of decomposed fish. The evidence indicates that the decomposition occurred at your firm's facility. Each of the four lots of fish found to be decomposed was received from a different supplier. Additionally, two of the lots of fish were in your firm's cooler for about six and eight days, respectively, before they were sampled by FDA. The presence and storage of decomposed fish in your cooler is a serious deviation from good manufacturing practice (GMP) regulations for food manufacturers (Title 21, Code of Federal Regulations, Parts 110.80).

Please advise this office in writing, within fifteen (15) working days of receipt of this letter, of the measures you have taken to preclude distribution of adulterated fish. We request that your response also address the storage and handling of fresh fish at your firm. You may FAX your

response to (510) 337-6707. Please direct your response to Ms. Erlinda Figueroa, Compliance Officer. If you wish to discuss this matter further, you may contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Steven G. Kendall
Acting District Director

cc VIA CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Michael Willing, General Manager
Royal Hawaiian Seafood
1155 Indiana Street
San Francisco, CA 94107